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18351 U.S.PTO 012004

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EU 768441901US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Thanhhung N	Le	10312 Oak Shade Ct. Mechanicsville, VA 23116

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Monitoring Apparatus For A Package

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City		State		Zip	
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5585 U.S.PTO 60/537297 012004

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 8

☒ Drawing(s) *Number of Sheets* 8

☐ Application Data Sheet. See 37 CFR 1.76

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☐ Other (specify) _____

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Respectfully submitted,

SIGNATURE D Bow

Date 1/20/04

REGISTRATION NO. 46,432 *(if appropriate)*

TYPED or PRINTED NAME Donald L. Bowman

Docket Number: CPG 03-30 MB PROV

TELEPHONE 301 497-1379

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Application Number	
Filing Date	
First Named Inventor	Thanhhung N. Le
Examiner Name	
Art Unit	
Attorney Docket No.	CPG 03-30 MB PROV

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1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	160.00

SUBTOTAL (1) ($) 160.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =		X =
Independent Claims		- 3** =		X =
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
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1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
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SUBMITTED BY				(Complete *(if applicable)*)	
Name *(Print/Type)*	Donald L. Bowman	Registration No. *(Attorney/Agent)*	46,432	Telephone	301 497-1379
Signature	D Bow			Date	1/20/04

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MONITORING APPARATUS FOR A PACKAGE

BACKROUND OF THE INVENTION

[0001] The invention teaches an apparatus for monitoring the removal of contents from a package, such as a pharmaceutical package.

[0002] The use of blisters to package items, such as pharmaceutical pills, is well known. United States Patent No. 6,244,462 issued to Ehrensvard et al and assigned to Cypak illustrates some of the features of an electronic medication dispense sensing device to monitor the removal of pills from a blister package. However the Ehrensvard patent has several shortcomings. First, the sheet-like envelope used to print the electrical circuit is difficult to fold and retain in a folded position. Second, the envelope limits the number of package shapes and configurations due to bulk of the folded envelope. Third, after the blister package is secured to the envelope it is difficult to test the monitoring circuit and remove the blister package and its contents if the circuit fails. For at least these reasons, there is a need to improve the design and method of making a monitoring apparatus for a package.

SUMMARY OF THE INVENTION

[0003] The invention teaches an apparatus for monitoring the removal of contents from a package and a method of making the apparatus.

BRIEF DESCRIPTION OF THE FIGURES

[0004] Additional features of the invention will become more apparent in the description below contain herein and can be further understood by reading the accompanying figures, wherein like characters represent like parts throughout the several views.

[0005] Figure 1 is a top plan view of a monitoring substrate according to the invention.

[0006] Figure 2 is a top plan view of a monitoring substrate with an monitoring circuit formed on the substrate.

[0007] Figure 3 is a top plan view of monitoring substrate with a digital processing unit in communication with the monitoring circuit.

[0008] Figure 4 is a top plan view of a package substrate according to the invention.

[0009] Figure 4B is a bottom plan view of the other side of said package substrate of Figure 4.

[0010] Figure 5 is a perspective view of a blister package.

[0011] Figure 6 is a top plan view of a blister package inserted into the package substrate.

[0012] Figure 7 is a perspective view of the monitored package partially inserted into an outer sleeve.

[0013] Figure 8 is a top plan view of another embodiment according to the invention.

DESCRIPTION OF THE INVENTION

[0014] Figure 1 illustrates a monitoring substrate 10 formed from any suitable material, such as paper, paperboard, composite material, plastics, etc. An exemplary material is formed from EasySeal Plus, manufactured by MeadWestvaco Corporation, Stamford, CT. Optional perforated regions 12, hereinafter referred to as "gates" are illustrated formed on a first surface 11 of the substrate 10. These gates 12 assist with removal of items from the package. In addition, optional embossed or partially raised or indented areas12, are also illustrated.

[0015] Figure 2 illustrates an exemplary monitoring apparatus formed on the top surface 11 of the substrate 10. In an exemplary embodiment, an electrically conductive circuit is formed on the substrate to form a monitoring substrate 20. The electrical circuit is formed of any suitable conductive material, such as conductive ink or conductive metals or any suitable combination. An exemplary circuit design includes a ground region 21 as illustrated on one end of the

monitoring substrate 20. Connection regions 22 for connecting to a digital processing unit 30 (see Figure 3) to the electrical circuit are also illustrated. Monitoring circuits 23 leading to each gate region 12 are illustrated. A conductive region 24 is illustrated over each gate 12. An optional enlarged conductive region 26 is illustrated toward the lower portion of the monitoring substrate 20. The enlarged region 26 could facilitate folding the monitoring substrate 20 in that region. An optional electrical switch 28 region is illustrated covering the embossed areas 13 of the monitoring substrate. The electrical switches 28 allow additional digital information to be collected from the monitoring substrate 20 and will be discussed in more detail below. It is to be understood that if a conductive material, such as an Aluminum foil backed blister package is secured directly to the monitoring substrate over the electrical circuit than a dielectric layer must be placed between the two conductive materials.

[0016] Figure 3 illustrates an exemplary digital processing unit 32 in electrical communication with the monitoring substrate 20 to form a monitoring apparatus 30. The digital processing unit 32 could comprise numerous configurations. For example, the processing unit 32 could include one of more of the following features, an internal or external power source, such as a battery, a memory storage device, a digital processing unit, an electrical signal output unit, a digital signal output device, such as audio device or visual display, an antenna, a modem, a clock, a processor controller, transmitter, one or more computer programs, as well as other well known digital and analog devices.

[0017] Figure 4 illustrates an exemplary packaging substrate 40 with a first surface 41. Apertures 42 are illustrated in a central region of the packaging substrate 40. Optional conductive regions 44 are illustrated at the lower end of the substrate 40. Optional aperture 43 is also illustrated to allow the digital processing unit 32 to extend through the package substrate 40.

Figure 4B illustrates the opposite side 45 of the packaging substrate. Text can be added to this surface of the substrate, such as the question "How do you feel since taking your last pill?" and answers, "Better," "Worse," "Same," and "Not sure" printed adjacent to the various conductive regions 44.

[0018] Figure 5 illustrates an exemplary blister package 50. A blister has a top surface 52 with a blister cells 53 extending from the top surface 52 with an end region 56. An item, such as a pill, is retained in the blister cell 53 by a backing material 54 secured to the bottom surface of the blister. The blister is typically formed from a substrate such as a thermo-formed plastic. A backing material 54 is typically made from foil, paperboard or other suitable material and is secured to the bottom of the blister. If the backing material 54 is conductive a dielectric layer must separate the backing material 54 from the conductive surfaces of the monitoring apparatus 30.

[0019] Figure 6 illustrates a blister package 50 secured to the packaging substrate 40 to form a package 60. The blister cells 53 ideally extend through the package substrate 40. The blister package 50 can optionally be secured to the packaging substrate 40 by adhesive or other suitable means.

[0020] According to a first exemplary embodiment, the package 60 is secured to the monitoring apparatus 30. The digital processing unit 32 ideally extends through the opening 43 of the package 60. The electrical circuits of the monitoring apparatus 30 are aligned with the blister cells 53 and the conductive regions 44 of the package 60. To remove an item 56 from the monitored package 60, the item 56 must be pushed through the backing material 54, and through the gate region 24 of the monitoring apparatus 20. In an exemplary method of operation, the digital processing unit 32, continuously or periodically sends a signal to each gate region 24. If

an item 56 has been removed, the resistance of an individual circuit will be high, as the gate 12 and the conductive material 24 have been removed. Thus little or no electrical signal will be returned to the digital processing unit 32 via the ground region 21. If the digital processing unit 32 is programmed with specific resistance levels, than the processing unit 32 can determine if an item 56 has been removed or not from the package 60 by measuring the resistance level of a particular monitoring circuit. By keeping track of which items have been removed the processing unit 32 can monitor and detect each successive removal. The digital processing unit 32 could also record the time and store it to a memory unit or transmit it to an external device (not illustrated). In addition, the unit 32 can record any closure of the switch region 28 on the monitoring apparatus. The switch 28 can be closed, by pressing or manipulating the conductive regions 44 on the monitored package 60. Switch closure 28 information can be stored in the memory or transmitted to external devices as well. The digital processing unit can limit the time period to monitor movement of the switch or limit the duration of time that it records switch movement to for example 1 minute or less. By tracking the removal of an item 56 and recording answers to the questions printed on the package, via the switches 28, input on the effectiveness of a pill, such a drug undergoing trials, can be recorded. It is to be understood that the above description is but one of many way to program and monitor the contents of the package 60.

[0021] Figure 7 illustrates the package 60 partially extended from an optional outer sleeve 100. It is to be understood that the monitored package could be further packaged into many different configured outer sleeves 100. Ideally, the monitored package 60 would be placed in a child resistant outer sleeve. An exemplary configuration of the monitored package 60 and outer sleeve 100 could include a Dosepak (TM) container design manufactured by MeadWestvaco Corporation of Stamford, CT more fully described in United States Patent No. 6,047,829. It is to

be understood that the outer sleeve could further container communication gear, an external power source, and numerous apparatuses to allow it to communicate with a computer or network, such as a phone.

[0022] It is to be understood that a one piece substrate with two regions 110, 140 could be used to secure a blister package (not illustrated) between the substrates 110, 140. A monitoring substrate 30 (not illustrated) as described above could then be secured to the base of substrate 140. In this embodiment, no dielectric layer would have to be placed between the backing material 54 of the blister package 50 and the electrical circuit on the monitoring substrate 30.

[0023] Once given the above disclosure, many other features and additional embodiments of the invention will become apparent to the skilled artisan. Such features and additional embodiments are therefore, considered to be a part of this invention, the scope of which is to be determined by the following claims.

CLAIMS

1. An apparatus comprising a monitoring substrate with a patterned conductive region further comprising a ground region; a monitoring circuit, a digital processor communication region.

2. The apparatus of claim 1 further comprising at least one input region.

3. The apparatus of claim 1 wherein said monitoring substrate is in electrical communication with a digital processing unit.

4. An apparatus comprising:

a monitoring substrate with a patterned conductive region further comprising a ground region; a monitoring circuit, and a digital processor communication region; and

a digital processing unit in electrical communication with said monitoring substrate.

5. An apparatus comprising:

a monitoring substrate with a patterned conductive region further comprising a ground region; a monitoring circuit, and a digital processor communication region;

a digital processing unit in electrical communication with said monitoring substrate; and.

a blister package comprising a one or more blister cells secured to said monitoring substrate wherein said monitoring circuits are aligned with said blister cells and said monitoring circuits are configured so that they are substantially destroyed when an item is removed from the blister package.

6. The apparatus of claim 5 wherein a dielectric material separates the back of said blister package from any conductive portion of said monitoring substrate.

7. The apparatus of claim 6 wherein said patterned conductive regions comprise conductive ink.

ABSTRACT

The invention teaches an apparatus for monitoring the removal of contents from a package and a method of making the apparatus.

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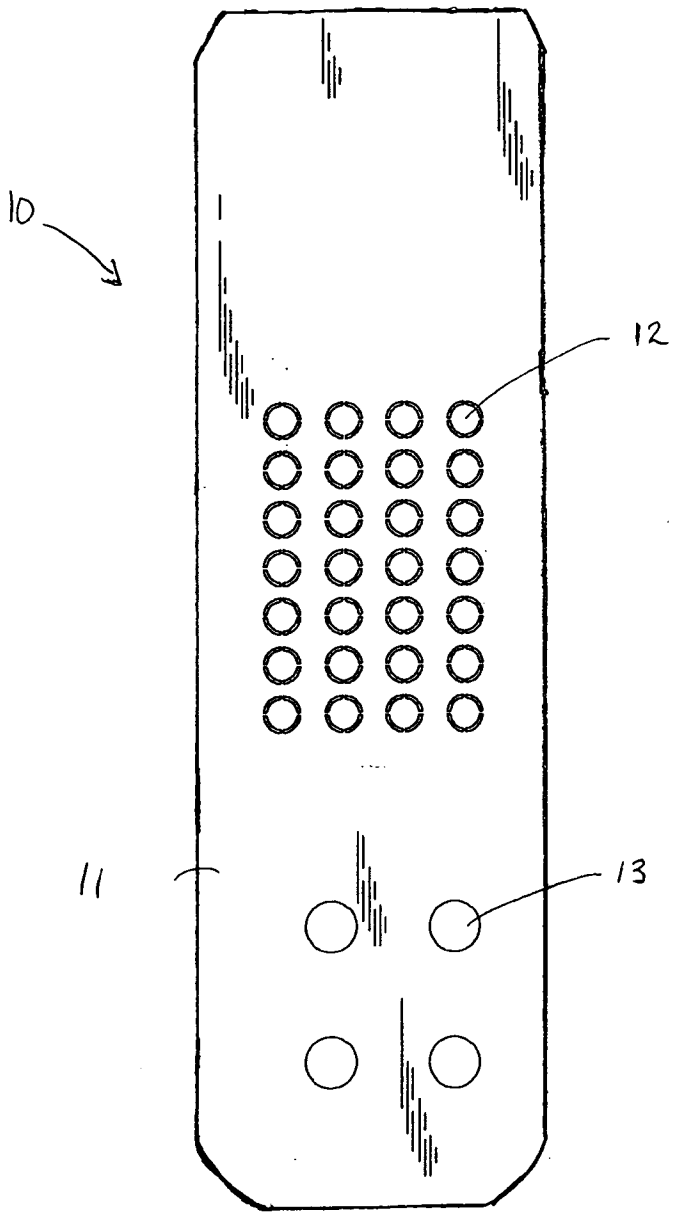


Figure 2

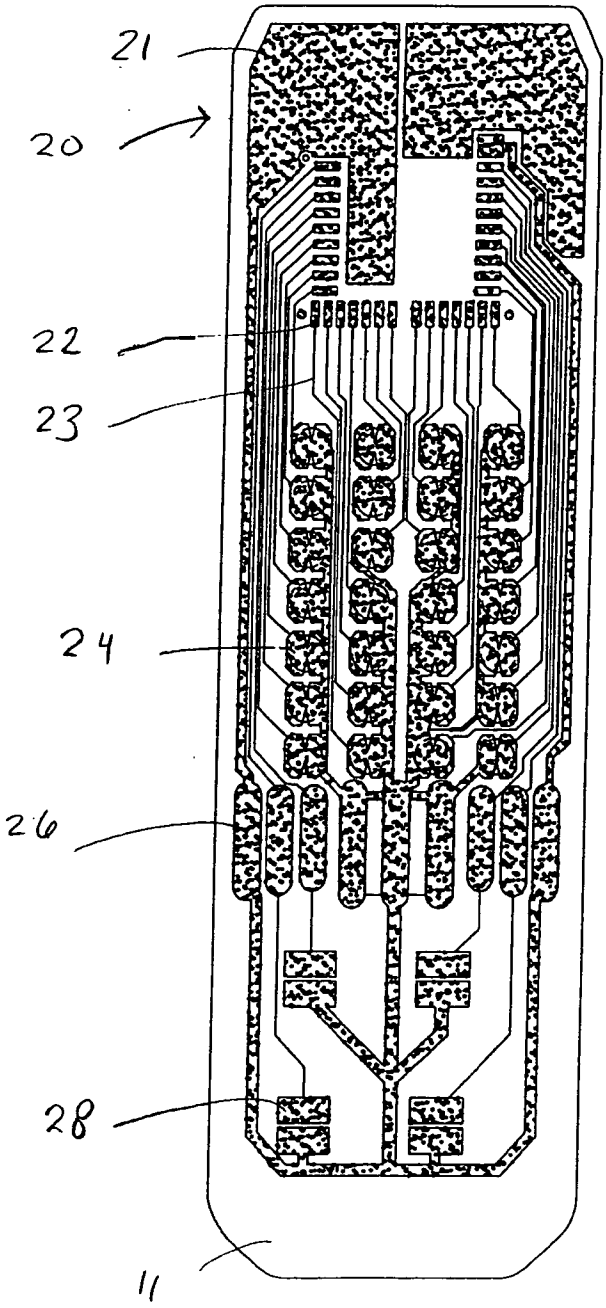


Figure 3

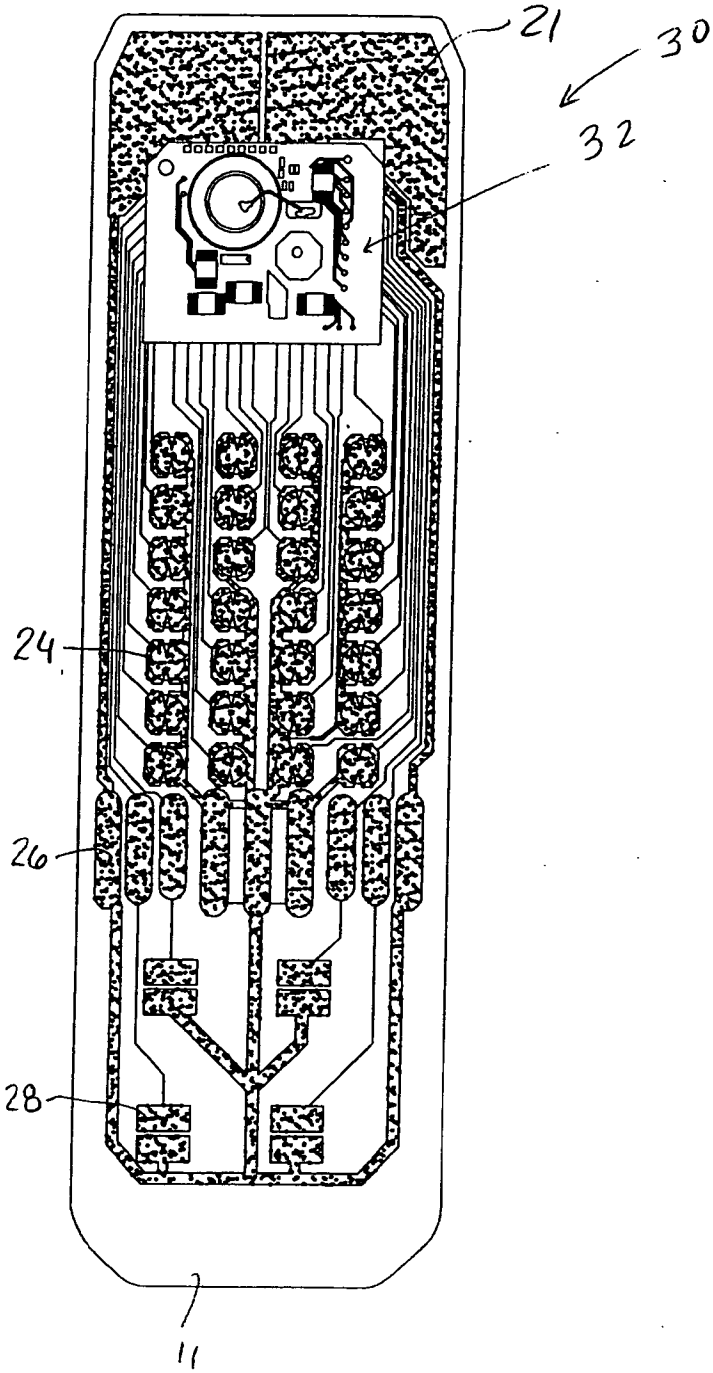


Figure 4

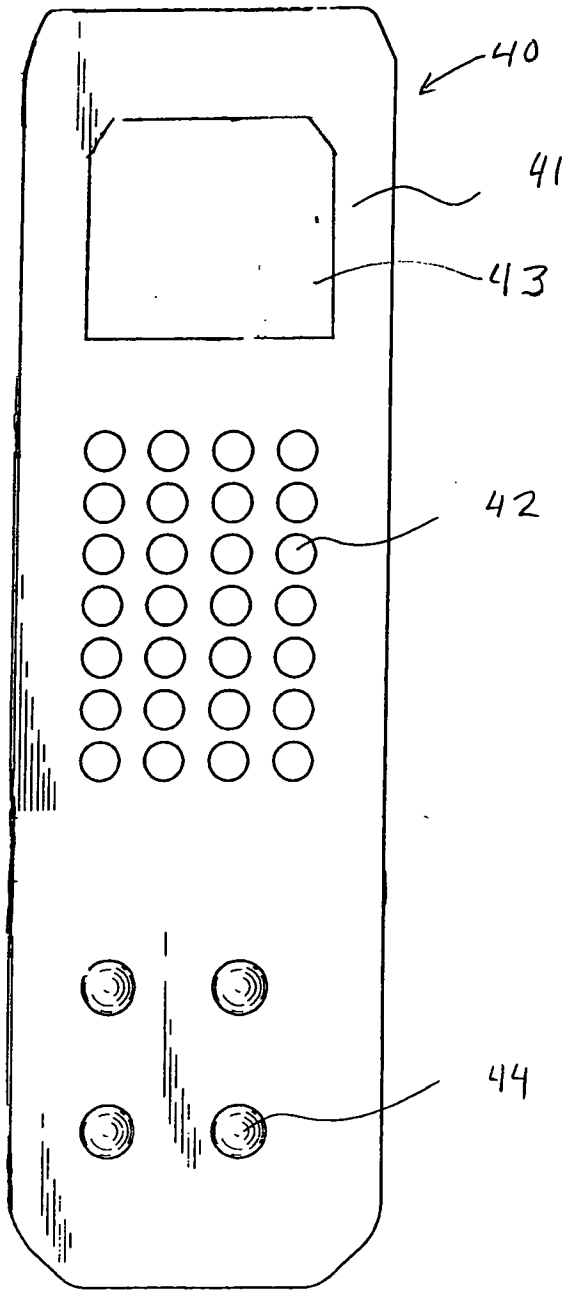


Figure 4B

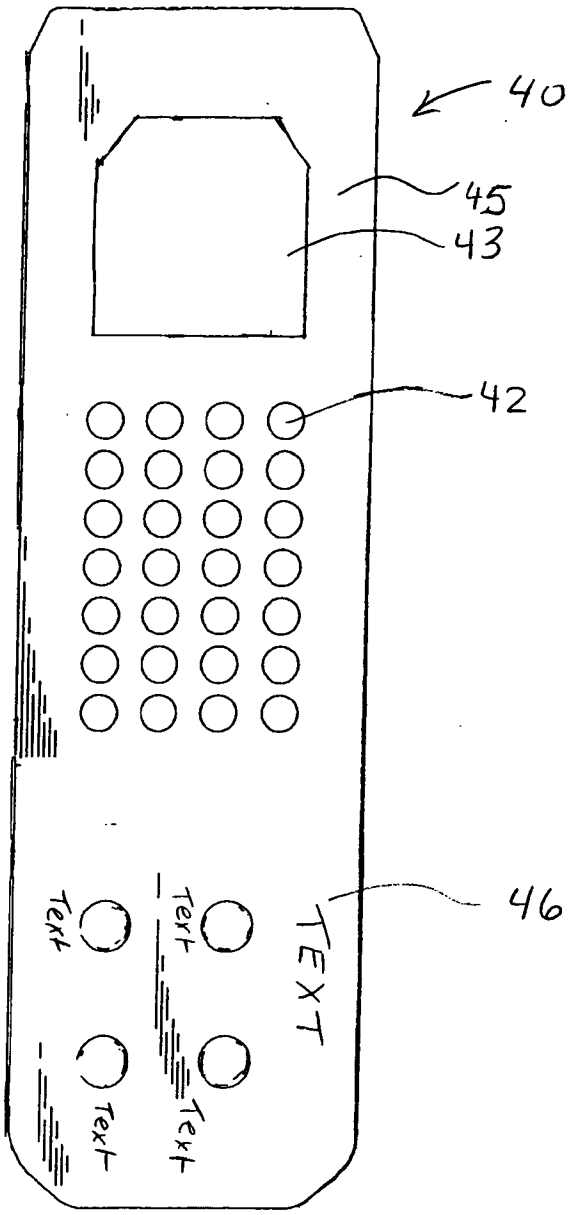


Figure 5

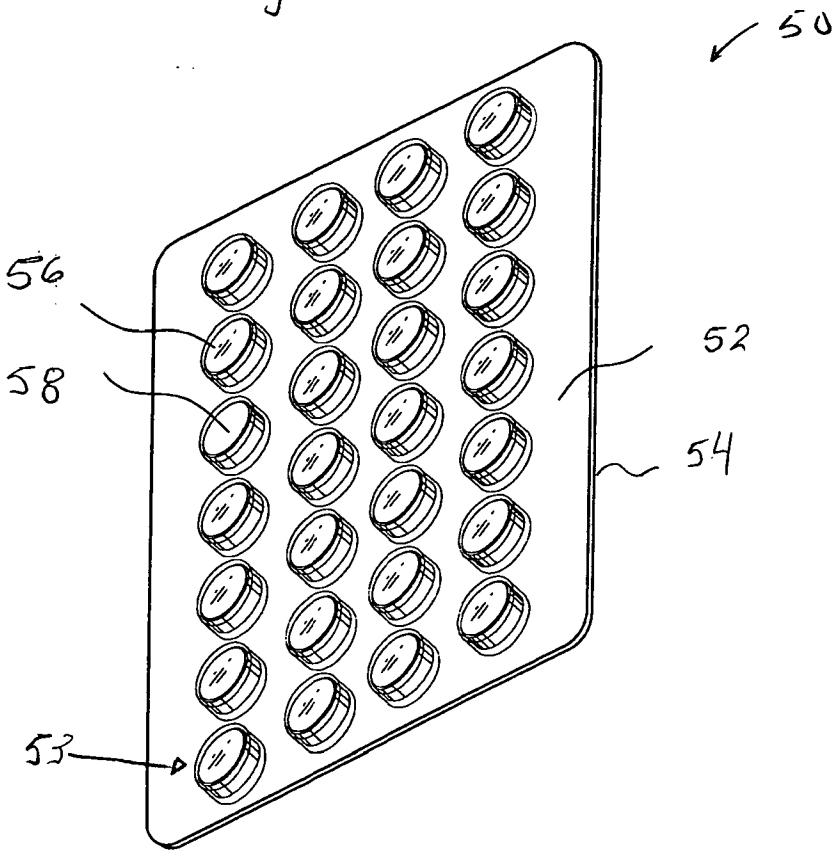
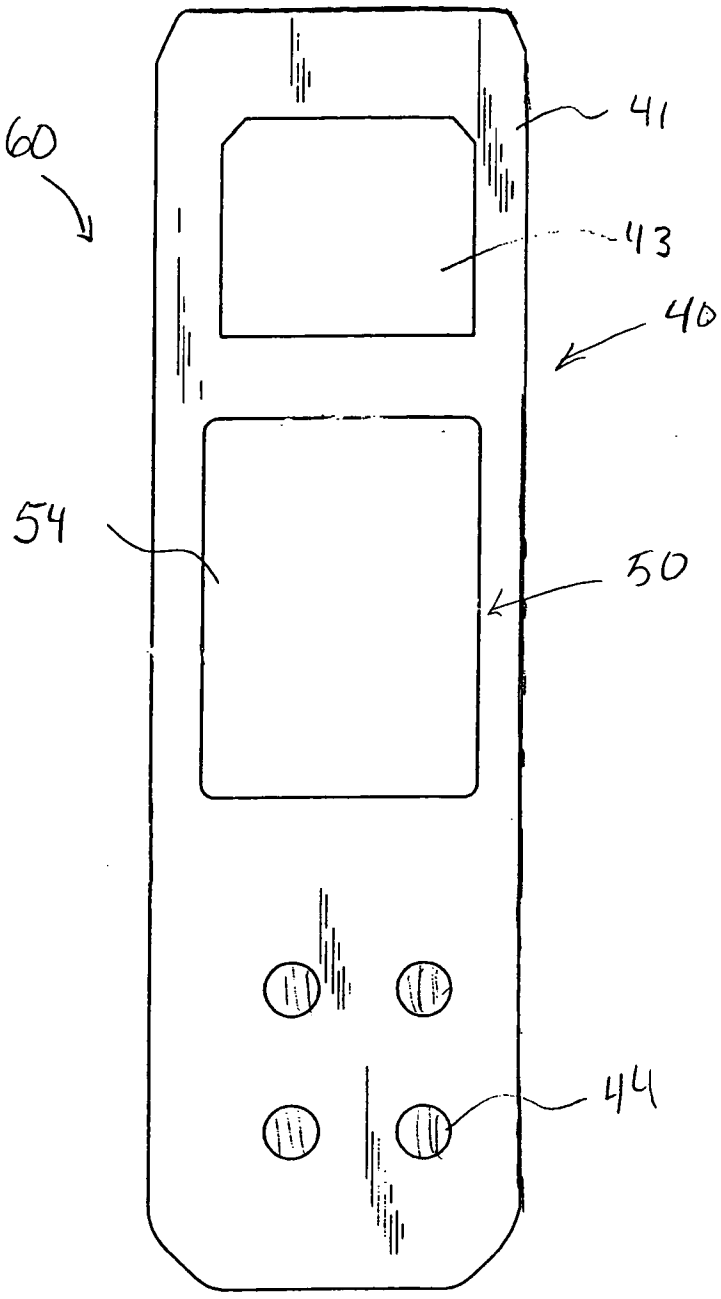


Figure 6



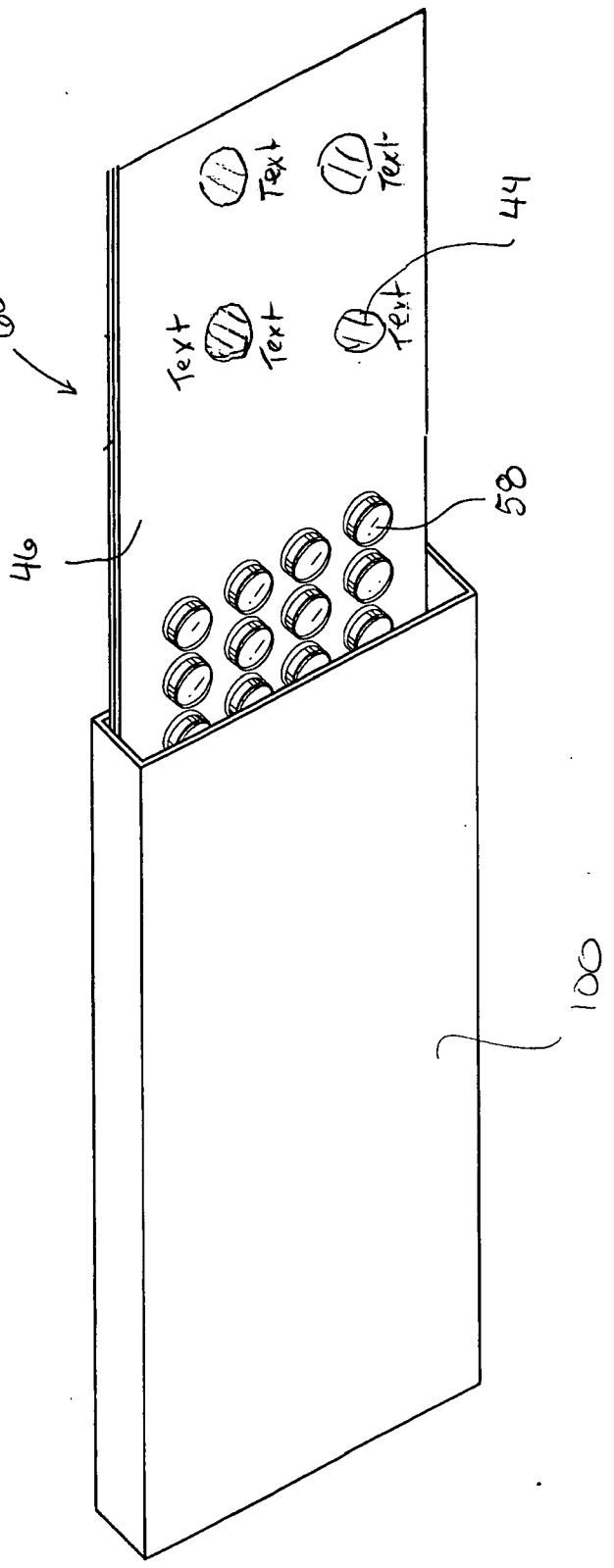


Figure 7

Figure 8